



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

#24

FEB 14 2002

Food and Drug Administration
Rockville MD 20857

Re: Axert
Docket No. 02E-0019

The Honorable Q. Todd Dickinson
Director of U.S. Patent and Trademark Office
Commissioner for Patents
Box Pat. Ext.
Washington, D.C. 20231

Dear Director Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 5,565,447 filed by Almirall Prodesfarma S.A. under 35 U.S.C. § 156. The human drug product claimed by the patent is Axert (almotriptan malate), which was assigned new drug application (NDA) No. 20-001.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in *Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224 (E.D. Va. 1989), *aff'd*, 894 F. 2d 392 (Fed. Cir. 1990).

The NDA was approved on May 7, 2001, which makes the submission of the patent term extension application on July 3, 2001, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Marina Velentgas Schneller
Venable, Baetjer, and Howard, L.L.P.
1201 New York Avenue, NW, Suite 1000
Washington, DC 20005-3917